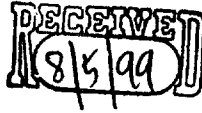




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August 4, 1999



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Express Mail Label No.

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Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. S.W.
Washington, D.C. 20204

RE: Notification of marketing a dietary supplement that bears on its label or its labeling a statement provided for in section 403 (r) (6) of the Federal Food, Drug and Cosmetic Act.

Dear FDA Consumer Safety Officer:

USANA, Inc. submits this notification for its dietary supplement products that bear statements of nutritional support in accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

Manufacturer of Dietary Supplement: USANA, Inc.
3838 West Parkway Blvd.
Salt Lake City, Utah 84120-6336

Name of Dietary Supplements: (including brand name) "ActiCal Chewable", "BiOmega-3", "Body Rox", "Iron 28", "Palmetto Plus", "PhytoEstrin", "SoyaMax."

Text of Statements Being Made for "ActiCal Chewable":

"Calcium, magnesium, vitamin D, and cofactors provide complete nutritional support for optimal bone development and maintenance."

"Calcium is the most abundant mineral in the body and plays many roles in maintaining healthy body structure and metabolism."

"Calcium is needed for blood clotting, nerve function, muscle contraction and relaxation, enzyme regulation and membrane permeability."

97S-0162
Also see docket 97S-0163

LET 4060

“Daily supplementation of calcium is important to ensure adequate calcium levels in the body, especially for postmenopausal women, lactating women, and both sexes during the years of building bone mass.”

“Mature bone is a complex, highly mineralized matrix composed primarily of collagen and other connective tissues. Calcium and magnesium are deposited in this matrix to give the bone strength and density.”

“Magnesium contributes to bone mass and also is critical for the proper function of vitamin D.”

“Vitamin D must be present to enhance the absorption of calcium in the small intestine and for the utilization of calcium in bone formation.”

“Silicon plays both a metabolic and structural role in the development of bone, cartilage, and connective tissue.”

“USANA’s new ActiCal Chewable is designed to overcome calcium deficits and to provide the complete nutritional support you need to help your body build and maintain healthy bones throughout life.”

Text of Statements Being Made for “BioOmega-3”:

“Supplementation of EPA and DHA fatty acids with BiOmega-3 capsules can support cardiovascular health, optimal neural growth and development, and maintain good joint health by increasing the intake of the right amounts of these important fatty acids.”

“EPA has been shown to support healthy cardiovascular function through the effects of beneficial prostaglandins that are made from it.”

“The marine polyunsaturated fatty acids also promote healthy clotting function and support circulatory system health in the blood vessels.”

“EPA is the precursor for the series 3 prostaglandins, which support healthy blood pressure, cholesterol and triglyceride levels, kidney function, inflammatory response, and immune function.”

“Supplementation of the omega-3 fatty acids as fish oil has been tested in many clinical trials and has been shown to be effective in supporting healthy joints.”

“Some health care authorities are recommending that infant formulas be fortified with DHA to support health and development of the nervous system.”

“The omega-3 fatty acids also are an important structural component of the retina and therefore are essential for the development and growth of the eye.”

Text of Statements Being Made for “Body Rox”:

“A comprehensive and convenient single tablet formula containing all the necessary vitamins, minerals, and antioxidants for optimum health in the teenage years.”

“In adolescence, the B vitamins are needed in increased amounts, especially by boys, to meet the extra demands of energy metabolism and muscle tissue development.”

“Vitamin C is essential for the immune system and for the absorption of iron, while vitamin A, also known as beta-carotene, is important in vision and in the development of healthy skin.”

“For adolescents, the B vitamins are needed in advanced amounts, by both boys and girls, to meet the extra demands of growth and development.”

“Folic acid is also important for teenaged females as they move into the child-bearing years.”

“Calcium intake during adolescence and early adulthood can establish a life-long pattern for bone integrity.”

“It is designed to work in conjunction with a healthy diet to provide the teenager’s body with the proper combination of nutrients needed for optimum performance from all the body’s cells throughout the life span.”

Text of Statements Being Made for “Iron 28”:

“Formulated for use by pregnant and lactating women. The primary function of this trace mineral in the body is in the formation of hemoglobin, the oxygen-binding pigment in red blood cells (RBC’s).”

“Iron is also necessary for the formation of myoglobin (muscle cell pigment) and is essential in the action of important metabolic enzymes.”

Text of Statements Being Made for “Palmetto Plus”:

“Immediate and long-term prostate support for men.”

“Palmetto Plus is a formulation that combines saw palmetto with lycopene and soy isoflavones. The result is a “full-spectrum” product for promoting overall prostate health.”

“Research has shown that saw palmetto inhibits the production of the enzyme 5-alpha-reductase, which is a catalyst for the conversion of the testosterone to dihydrotestosterone.”

“Palmetto Plus provides powerful support to the male body in maintaining overall prostate health.”

“Recently, a review of the efficacy and safety of saw palmetto supplementation in men with prostate problems revealed that about 80-90 percent of men treated with saw palmetto in 18 randomized clinical studies showed a positive correlation between saw palmetto and prostate health.”

“In addition to having a direct effect on the prostate, saw palmetto has a gentle and strengthening effect on the whole of the male reproductive and urinary systems.

Text of Statements Being Made for “PhytoEstrin”:

“Provides the benefits of isoflavone activities such as the promotion of healthy blood lipid levels, support of bone health, and moderation of hormone cycles.”

“USANA’s PhytoEstrin formulation of soy isoflavones combined with herbal extracts of black cohosh, licorice root, chasteberry, and dong quai may be a valuable aid in promoting healthy bone structure and good cardiovascular health while providing support during menstruation and in the peri- and post-menopausal years.”

“The phytoestrogens, although not as potent as the human estrogens produced by the human body, may be able to moderate the influence of estrogen and thus be a stabilizing factor throughout the hormonal cycles. This stabilization may promote the long-term health of the reproductive system, including during peri- and post-menopause.”

“Phytoestrogens may also have a positive effect on maintaining bone mass into the mature years.”

“The primary isoflavones are genistein and daidzein, both have been shown to act as weak estrogens in the in the body. As such, they can moderate the effects of the decline in estrogen production, including bone porosity, cholesterol and LDL levels. Daidzein has also been shown to restrict the development of new blood vessels.”

“Widely recognized in Europe, Black cohosh is the most widely used and thoroughly studied natural support during menopause.”

“In Asia, dong quai has been used for millennia as a traditional “female” support to promote healthy pregnancy and delivery.”

“The (Licorice Root) extract has estrogenic activity and may help to regulate the estrogen-progesterone ratio.”

“Chasteberry powder contains essential oils and can be helpful for normalizing the menstrual cycle.”

“For many women, PhytoEstrin may support menstrual health during the childbearing years and may assist in improving the quality of life during the transition of menopause in addition to a program of regular exercise, a proper diet, and nutritional aids including vitamin E, pantothenic acid (vitamin B5), and supplemental calcium.

Text of Statements Being Made for “SoyaMax”:

“Recommended servings of SoyaMax may have a positive effect on heart and bone health and menopausal support.”

“In addition to supplying high-quality protein as a food, as a supplement, or as isolated soy protein, soy has numerous health benefits. A daily intake of as little as 25 grams has been shown to have a positive effect on blood cholesterol levels.”

“Soy protein has antioxidant effects and has also been shown to suppress the oxidation of LDL and cholesterol.”

“Soy protein may also help to promote bone health, primarily by causing much less calcium loss in the urine.”

“The diverse benefits of soy, including hormonal regulation, cholesterol level maintenance, and support for bone health, are key reasons why soy products are being advocated by the nutritional and medical communities alike.”

“Many of the health benefits of soy come from the numerous phytochemicals found in the bean. These compounds include protease inhibitors, which may protect cells from radiation and environmental pollutants, phytates, which may enhance the immune system, and saponins, which demonstrate antioxidant activity.”

“The important isoflavones in soy are daidzein and genistein. They attach to estrogen receptor sites and may aid in maintaining healthy hormone levels through the childbearing years and during menopause.”

“Isoflavones may also act as antioxidants and support healthy growth at the cellular level.”

John B. McCandless declares:

1. That he is Senior Vice President and Chief Operating Officer of Usana, Inc.

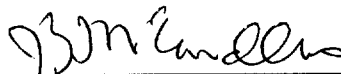
(hereinafter "applicant") and is authorized to make this declaration;

2. That information contained in this statement is complete and accurate, and that USANA, Inc. has substantiation that the statement is truthful and not misleading.

DATED this ____ day of August, 1999.

USANA, INC.

By:

A handwritten signature in dark ink, appearing to read "JBM McCandless", written over a horizontal line.

John B. McCandless
Senior Vice President and
Chief Operating Officer